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Assistant Commissioner for Patents
Washington, D.C. 20231

On May 17, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: Sylvia Arnold

PATENT
Attorney Docket No.: 021706-000810US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tony Wai-Chiu So et al.

Application No.: 10/124,197

Filed: April 16, 2002

For: PHARMACEUTICAL COMPOSITION

Customer No.: 20350

Confirmation No. 1659

Examiner: Sharmila S. Gollamudi

Technology Center/Art Unit: 1616

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Albert Zorko Abram, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.

2. I am currently employed by Connetics Australia Pty Ltd, the assignee of the subject application.

3. I am a Senior Chemist –Technical IP Associate and have been in pharmaceutical research since 1987. I have been employed doing dermatological product development for the last 16 years. My *Curriculum Vitae* is of record.

4. I have reviewed and analyzed the above-referenced patent application, and I am familiar with the contents therein.

5. It is my understanding that the Examiner alleges in the Office Action dated October 17, 2003 that, in the Declaration under 37 C.F.R. § 1.132 submitted on April 1, 2003 ("the 2003 Declaration"), Applicants did not provide the identity and amount of the components in the inventive foam formulation used for the side-by-side comparison with the foam formulation of Di Schiena (U.S. Patent No. 4,866,067). For the reasons set forth herein, the Examiner's concerns are overcome.

6. As described in the 2003 Declaration, the formulation set forth in column 3, Example 3(e) of Di Schiena, entitled "Foam," was prepared in our laboratory at Connetics Australia following the teaching of Di Schiena with an understanding of the foam art.

7. Exhibit A contains a true copy of a page from a Connetics' laboratory notebook, with the date redacted therefrom. As shown in Exhibit A, the Di Schiena foam ("comparative") was prepared according to the teaching set forth in Example 3(e) of Di Schiena. An accepted hydrocarbon propellant (*i.e.*, Propellant P70) was substituted for the chlorofluorocarbon propellant of Di Schiena at an amount to produce a foam of acceptable quality (*see*, the 2003 Declaration).

8. The foam as disclosed in the subject application ("inventive") was prepared in our laboratory according to the following formulation:

Component	% w/w
Minoxidil	4.75
Ethanol	53.645
Purified Water	31.410
Butylated Hydroxytoluene	0.095
Lactic Acid (90%)	1.00
Citric Acid	0.10
Stearyl Alcohol	0.50
Cetyl Alcohol	1.10
Polysorbate 60	0.40
Propylene Glycol	2.00
Propellant P70	5.00
Total	100.00

9. Exhibit B contains a true copy of a page from my notebook, with the date redacted therefrom, disclosing the formulation set forth in the table above.

10. As described in the 2003 Declaration, I have performed a side-by-side comparison of the inventive foam against the comparative foam and found unexpected properties in the

inventive foam that were not present in the comparative foam, including foam consistency, stability, and advantageous mechanical shear properties.

The declarant has nothing further to say.

Albert Zorko Abram

12 May, 2004
Date

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SK715

Experiment: 187/6

Title: Minoxidil Foam I.P. evaluation

Aim:

① Prepare a sample of the "Di-Sharma" formulation.
② Review low temperature stability results to date.

Experimental:

The following "Di-Sharma" formulation was prepared. Ref: 5% P70 replaced the 10% 114 propellant in the patent formula.

		Batch	Batch Qty 1/1/1
①	Minoxidil	93137	3.0 g
②	Nicotinic Acid-N-Oxide	23063	2.0 g
③	Propylene glycol	22583	9.0 g
④	Isopropyl alcohol	21645	4.5 g
⑤	Cetyl alcohol	95679	1.6 g
⑥	Stearic acid	21391	0.9 g
⑦	Laureth-4	24495	4.7 g
⑧	Water	–	64.1 g
	Propellant P70	25099	5.0 g

Items ① to ⑥ were mixed at room temperature and formed a clear solution.
Items ⑦ and ⑧ were added and the mixture was warmed to 80°C but a clear solution did not form.
On cooling this formed a thin lotion/gel.
When the propellant was added the thin gel/lotion gelled significantly forming a laminar surfactant structure not dissimilar to 70% SLES. Would this happen with propellant 12?
I don't know.

Experiment 10,

SOLTEC RESEARCH *Innovation in Drug Delivery*

Manufacturing Dossier
Strictly confidential

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Soltec Item description: 5% Minoxidil Mousse
Soltec Formula: F112/29/03
Soltec Batch Number: E126/10/01

Batch Record

	Phase 1						Beaker Tare: 276.82
1	Ethanol 100AG 22	22004	10.00	500.00	500.0		+ theoretical mass (g) 600.0
2	Polysorbate 60	21371	0.40	20.00	20.0		876.82.
3	Stearyl alcohol	21364	0.50	25.00	25.0		
4	Cetyl alcohol	21365	1.10	55.00	55.0		
	Phase 2				600.0		Ethanol added to correct for evap. losses. (total 876.8g)
5	Ethanol 100AG22	22004	43.645	2182.25	2185.7		
6	Butylated hydroxytoluene	21368	0.095	4.75	4.8		
7	Purified Water	16Jan-02	31.410	1570.50	1582.2		
8	Citric acid	21369	0.10	5.00	5.0		
9	Minoxidil	20105	4.75	237.50	237.8		Beaker tare: 1000.26
10	Lactic Acid (90%)	21363	1.00	50.00	49.9		+ theoret. mass (g): 4165.4
	Propylene Glycol	21367	2.00	100.00	100.0		5165.66
	Phase 3				4165.4		
	Propellant P70	20229	5.00	250.00			ethanol added to correct for evap. losses (total mass: 5.17kg)
	Total		100.00	5,000.00			

Aluminium PAM lined cans 65 x 125mm		1			
Valve YL 33383		1			